

recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a *new animal drug* if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(h) The term *animal feed* means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of: (1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug; (3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug; (4) the newness for its intended drug use in a different species of animal; (5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or (6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling

of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

(j) *Animals used only for laboratory research and laboratory research animals* mean individual animals or groups of animals intended for use and used solely for laboratory research purposes, regardless of species, and does not include animals intended to be used for any food purposes or animals intended to be kept as livestock.

(k) *Sponsor* means the person requesting designation for a minor-use or minor-species drug as defined in part 516 of this chapter, who must be the real party in interest of the development and the intended or actual production and sales of such drug (in this context, the sponsor may be an individual, partnership, organization, or association). Sponsor also means the person responsible for an investigation of a new animal drug. In this context, the sponsor may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs. Sponsor also means the person submitting or receiving approval for a new animal drug application (in this context, the sponsor may be an individual, partnership, organization, or association). In all contexts, the sponsor is responsible for compliance with applicable provisions of the act and regulations.

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 54 FR 22741, May 26, 1989; 64 FR 69190, Dec. 10, 1999; 72 FR 41017, July 26, 2007]

§510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.